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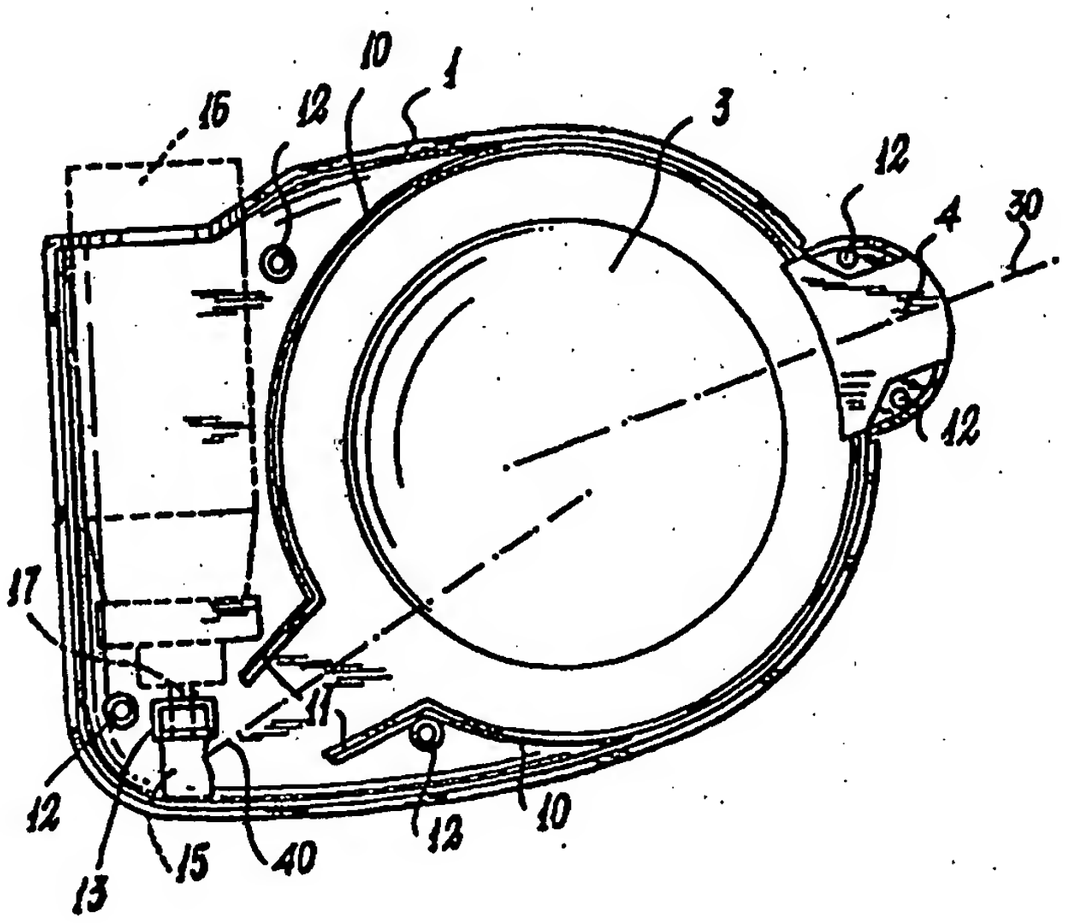

(57) Abstract

An aerosol nozzle, comprising a socket provided with a seat to house a hollow stem of an aerosol dispensing pressurized can, said nozzle being shaped as a T, consisting of an upper bar and of a vertical stem, characterized in that the hole of said nozzle through which the aerosol dose is discharged is inclined with respect to the plane normal to the axis of said vertical stem.

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NOZZLE FOR USE IN MOUTH-INHALING FOR AEROSOL MEDICAMENTS

The present invention relates to an aerosol nozzle, comprising a socket provided with a seat to house a hollow stem of an aerosol dispensing pressurized can.

Inhalation is the preferred system for delivering medicament particles into the lungs.

For this purpose pressurized cans containing the medicament and a propellant are used, the cans being provided with a metering valve which when manually operated dispenses metered doses of propellant-medicament mixture which atomizes through a nozzle as a finely powdered spray into the mouth of a patient.

It is generally known that only about 10% of the aerosol dose discharged by a pressurized can is capable to reach the lungs.

A similar percentage is expired or is deposited outside the oral cavity, whereas because of the impact of the high speed particles about 80% is deposited within the oropharyngeal cavity, swallowed systemically adsorbed and hence practically lost.

If the pressurized can is not used properly the quantity of medicament which reaches the site of action at the pulmonary level is further reduced and the therapeutic response is compromised.

Excessive aerosol depositing in the oropharyngeal cavity can also lead to undesirable effects either at systemic level as a consequence of the drug absorption, or at the local level, as in the case of corticosteroids, which can result in oral candidiasis.

The reasons for poor pulmonary penetration are known.

Even if a dispensing can for aerosol medicaments is used correctly, the availability of an inhaled medicament to the lungs depends largely on the size of the aerosol droplets.

The only particles that can penetrate into the lungs is any significant degree are those whose diameter is 1-5 thousandths of a millimetre (microns). An inhalation aerosol spray only contains a small amount of such particles as most of the medicament is bound to considerably larger droplets formed by a non-volatile propellant.

Thus, it is obvious that by reducing the droplet size of a spray it is also possible to reduce the particle size and hence to improve the pulmonary penetration of a medicament and the size of droplets is reduced as the volatilization of a propellant proceeds.

In an attempt to overcome the problems connected with the use of aerosol medicament, auxiliary delivery systems have been developed over the last decade for application to the nozzles of pressurized dispensing cans.

In the european patent EP-B-0475257 a mouth-inhaling device for use with pressurized cans for dispensing metered doses of medicament is described.

Said device is designed to favour the inhaling of a greater number of active particles and to avoid spraying the aerosol directly onto the mucosa of the oropharynx in order to safeguard the user against side effects deriving from direct spray into the mouth.

In this respect, the device has an expansion chamber shaped to create, by virtue of the speed at which the aerosolized material is expelled by the dispenser, a

vortex flow in which the particles remain in suspension for sufficient time to enable them to discharge their kinetic energy and allow substantial evaporation of the propellant, with a consequent reduction in the size and in the velocity of the particles, leading to a more efficient intrapulmonary delivery, while large size particles are centrifuged onto the walls of the chamber, to deposit on them.

The device comprises a body with a seat for housing a can provided with a stem for operating the can dispensing valve, a chamber for the collection and expansion of the aerosol dispensed by a discharge nozzle on the can, and a mouthpiece communicating with said chamber and projecting outwards from said body. The body has a substantially flat shape and the chamber is delimited by a curved wall, into a first peripheral portion of which there opens the inner end of the mouthpiece, and in a second peripheral portions of which, opposite the first, there is an aperture from which two walls extend outwards from the chamber to converge towards the can discharge nozzle and define a duct, the central plane of which is inclined to the central plane of said mouthpiece.

The aerosol dispensed by the can, when operated, penetrates into the expansion chamber and expands to circulate with a vortex flow which causes the solvent to evaporate and the flow movement to continue for a relatively long time, hence enabling only very small particles of the medicament to be drawn into the bronchial tree.

The structure and characteristics of the inhaler device are illustrated in Figure 1 to 4 in which:

Figure 1 is a perspective view of the inhaler device;

Figure 2 shows one of the two shells forming the device, viewed in the direction indicated by the lines 2-2 of Figure 1; and

Figure 3 and 4 are sections through the inhaler device on the lines 3-3 and 4-4 of Figure 1.

It can be seen from Figure 2 that in a peripheral portion of the curved wall 10, opposite that from which the mouthpiece 4 projects, there is an aperture from which two walls 11 and 21, respectively (Figure 4), extend outwards from the chamber to converge (Figure 2) towards the exit hole of the nozzle and define a duct for the medicament flow.

It is now unexpectedly found that the aerosol circulation with a vortex flow into the expansion chamber can be favoured and improved by a particular realization of the nozzle wherein the hole through which the aerosol dose is discharged is inclined (Figure 8).

In accordance with the present invention there is provided an aerosol nozzle having the shape of a T consisting of an upper horizontal bar and a vertical stem, said stem comprising a socket with a seat for housing a hollow stem of a pressurized can, characterized in that the hole of the vertical stem of the nozzle through which a dose of medicament discharged from a metering valve finds its way into the expansion chamber is inclined with respect to the hollow stem of the pressurized can.

Specific embodiments of the invention will now be described, with reference to the accompanying drawings, in which:

Figure 5 is a front view of the T shaped nozzle;

Figure 6 is a side view of the T shaped nozzle;

Figure 7 is a top view of the T shaped nozzle;

Figure 8 is a section view of the nozzle along lines A-A of the Figures 5 and 7, showing the socket provided with a seat to house a hollow stem of a pressurized can and the inclined hole through which a dose of medicament discharged from the valve enters into the expansion chamber.

The nozzle (1) is shaped as a T, consisting of an upper bar composed by two fins (2, 3) to be housed and retained in two seats provided in the two shells forming the device and of a vertical stem (4) shorter than the horizontal upper bar.

The vertical stem (4) comprises a socket (5) provided with a seat to house a hollow stem of a pressurized can.

In the thickness of the stem (4) is bored a hole (6) that connects the socket (5) with the expansion chamber of the device through the orifice (7).

The hole (6) is inclined with respect to the plane B normal to the axis of the vertical stem (4).

When a pressurized can has been housed in the device, with the valve stem inserted into the seat of the socket (5) of the nozzle (1) and the base of the can is pressed with one finger, the dispensing valve within the can opens and a measured quantity of aerosol is discharged.

The discharged aerosol passes through the inclined hole (6) and emerges through the orifice (7) as a cone whose axis is inclined with respect to the plane B.

The axis of the hole and of the emerging aerosol cone forms with the plane B an angle in the range of 20 to 30° and preferably of 27°.

The internal diameter of the hole (6) is in the range of 0.40 to 0.55 mm and is preferably of 0.42 to 0.52 mm.

The inclination of the hole is designed in a manner that the aerosol cone issuing from the nozzle orifice passes through the duct defined by the two walls 11 and 21 of Figures 3 and 4 extending outwards from the expansion chamber and converging towards the exit hole of the nozzle.

The inclination of the hole is designed in a manner that the axis of said aerosol cone corresponds with the central plane of the ducts.

It is so avoided any possible deviation of the aerosol jet resulting from the impact of a part of the aerosol cone against the diverging walls 11 and 21.

The aerosol cone penetrates into the expansion chamber and generates within the chamber a vortex motion which results in deposition of the largest particles on the walls whereas the other particles lose their layer of propellant and hence reduce in diameter with an increase of the respirable fraction.

CLAIMS

1. An aerosol nozzle, comprising a socket provided with a seat to house a hollow stem of an aerosol dispensing pressurized can, said nozzle being shaped as a T, consisting of an upper bar and of a vertical stem, characterized in that the hole of said nozzle through which the aerosol dose is discharged is inclined with respect to the plane normal to the axis of said vertical stem.

2. A nozzle as claimed in claim 1, characterized in that the axis of the hole and the plane normal to the axis of the stem form an angle in the range of 20 to 30° and preferably of 27°.

3. A nozzle as claimed in claims 1 and 2 wherein the internal diameter of the hole is in the range of 0.40 to 0.55 mm and preferably of 0.42 to 0.52 mm.

4. An aerosol nozzle substantially as herein described, with reference to, and as illustrated in, Fig.5 to 8 of the accompanying drawings.

5. A nozzle as claimed in claims 1 to 4 to be housed in a device for mouth inhaling medicaments dispensed as aerosols by pressurized cans, comprising a body with a seat for housing a can provided with a stem for operating the can dispensing valve, a chamber for the collection and expansion of the aerosol dispensed by a discharged nozzle of the can, and an inhalation mouthpieced communicating with said chamber and projecting outwards from said body, wherein the body is of substantially flat shape, che chamber si delimited by a curved wall, into a first peripheral

portion of which there opens the inner end of said mouthpiece, and in a second peripheral portion of which, opposite the first, there is an aperture from which two walls extend outwards from the chamber to converge towards the can discharge nozzle and define a duct the centre plane of which is inclined to the centre plane of said mouthpiece, characterized in that the aerosol discharged by the can circulates within the chamber with a vortex flow.

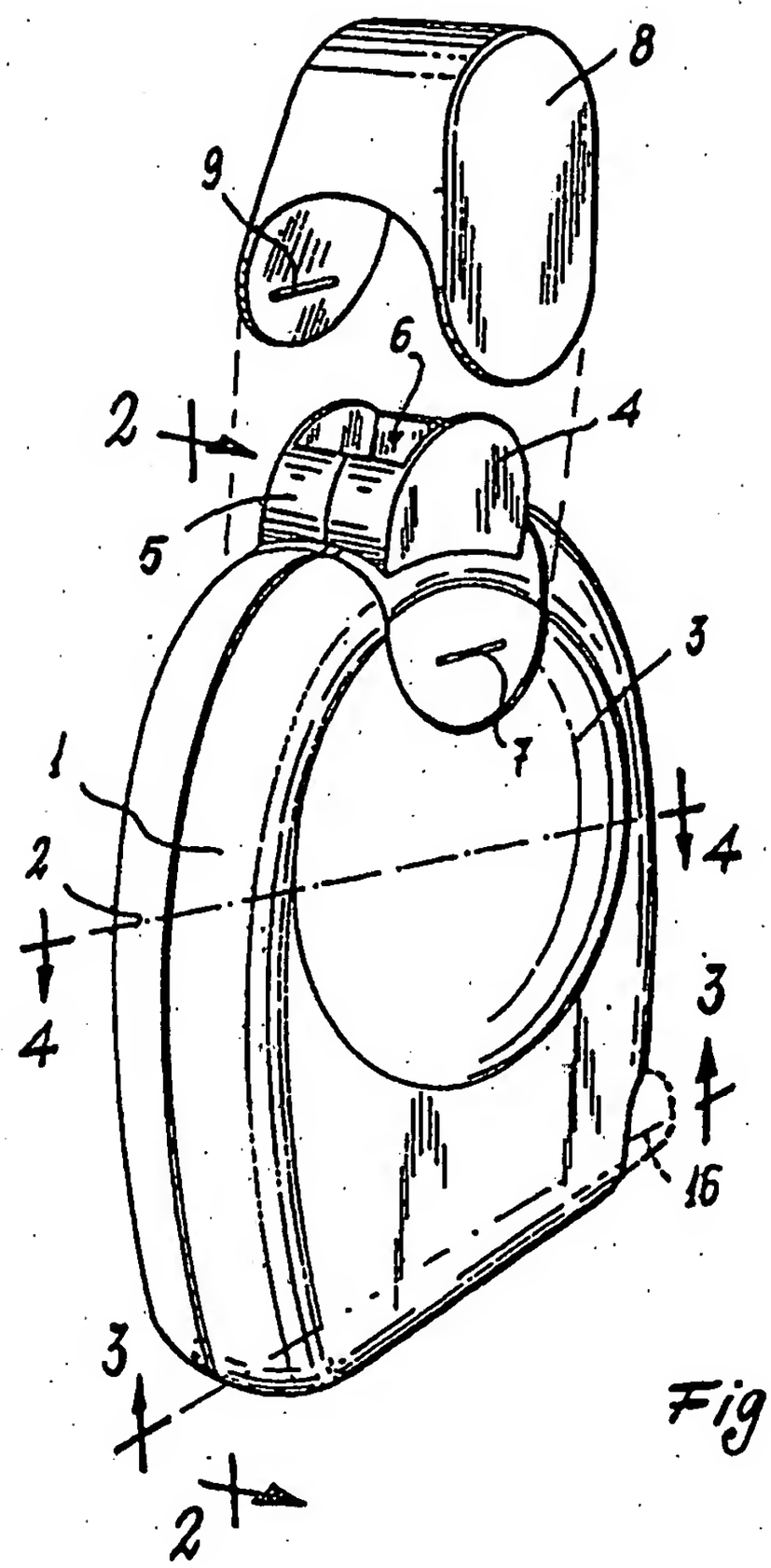

Fig. 1

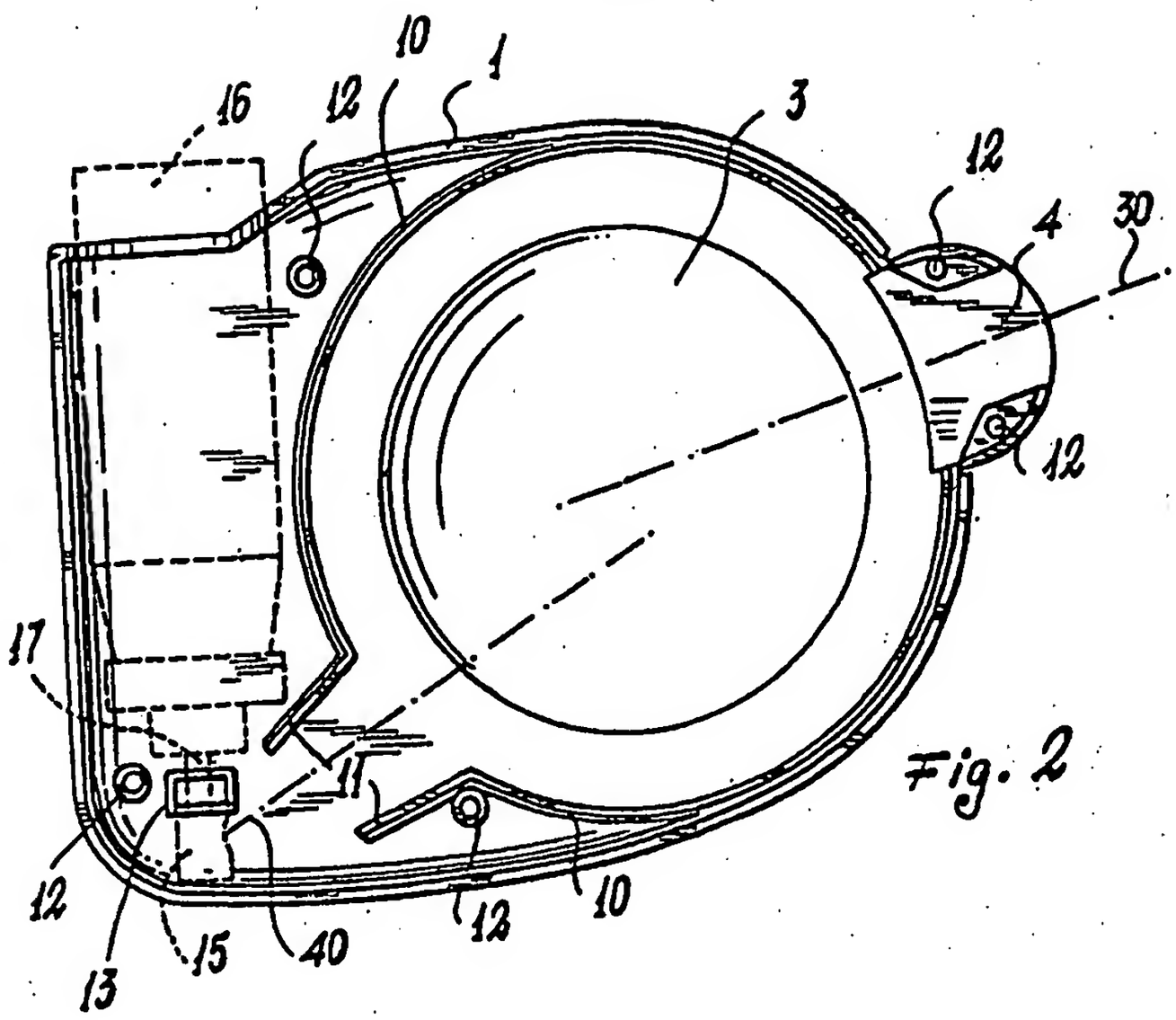

Fig. 2

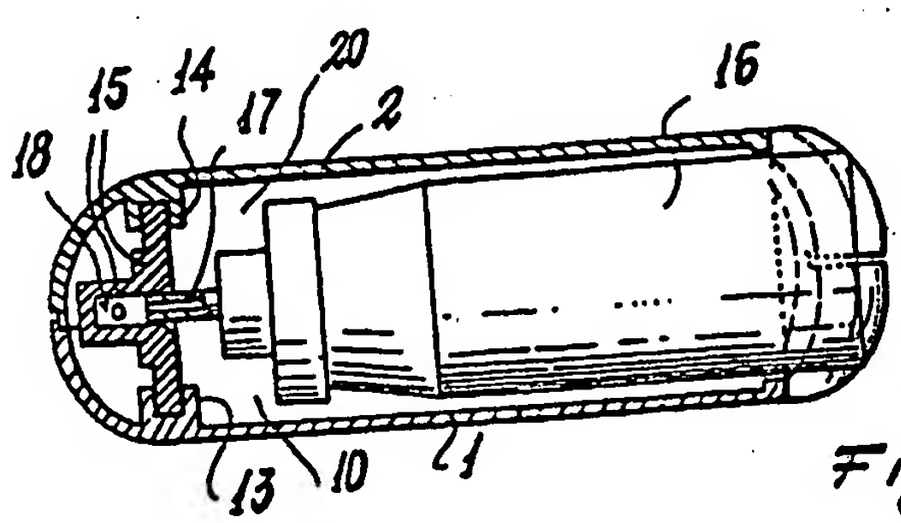

Fig. 3

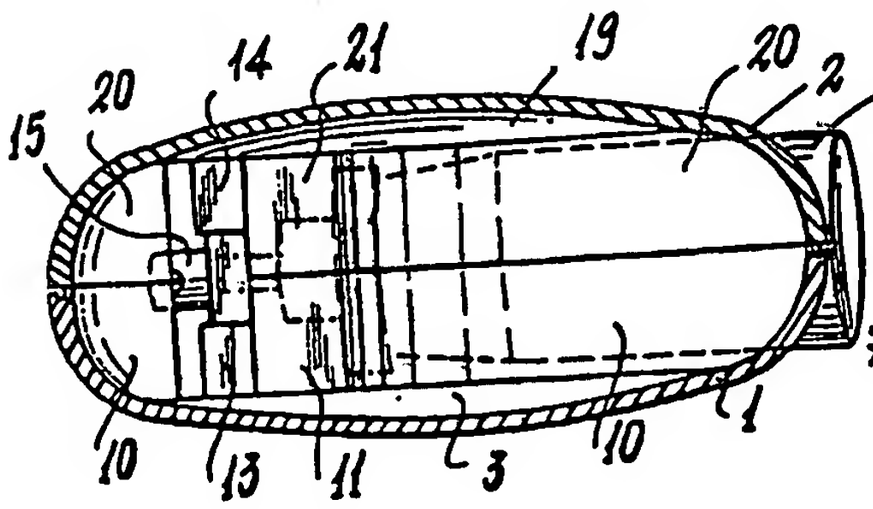

Fig. 4

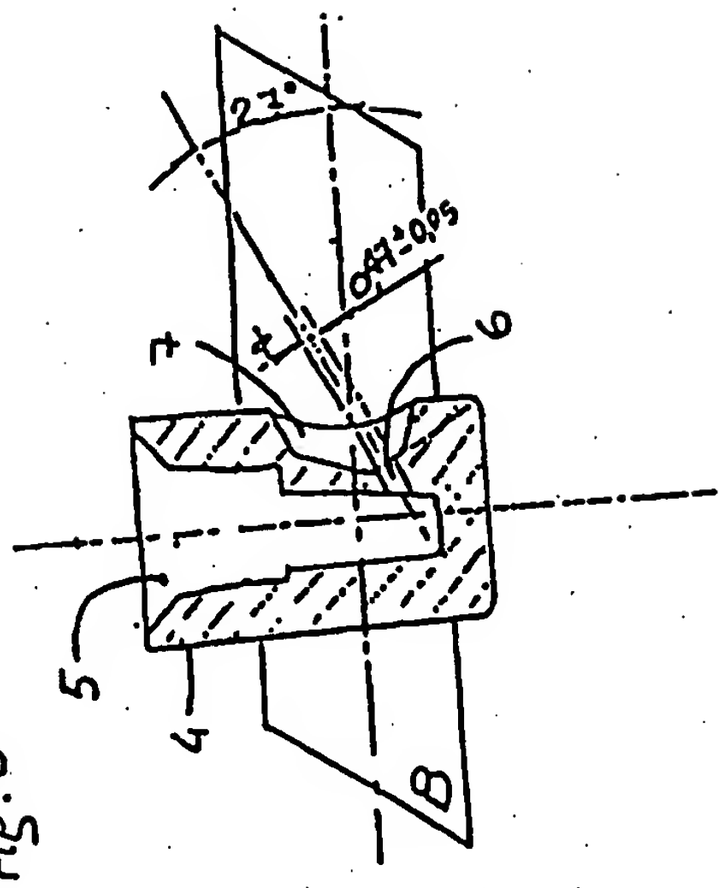

Fig. 8

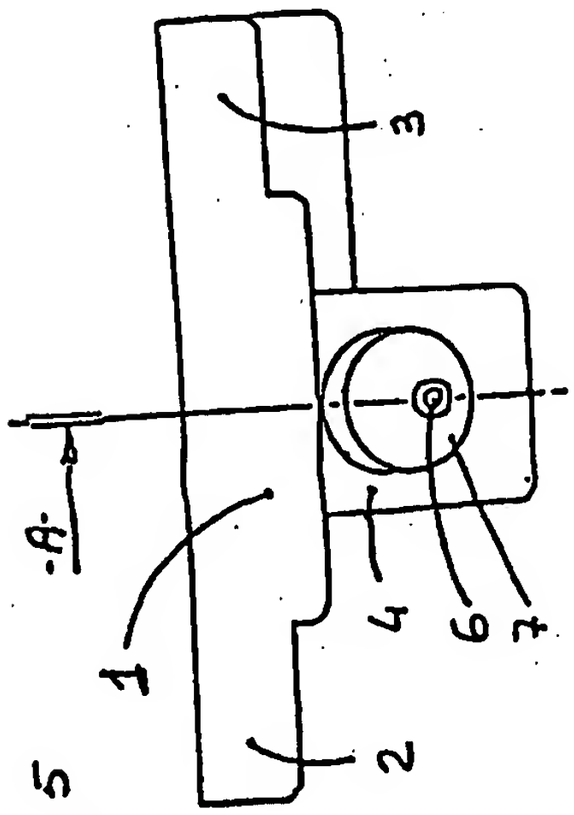

Fig. 5

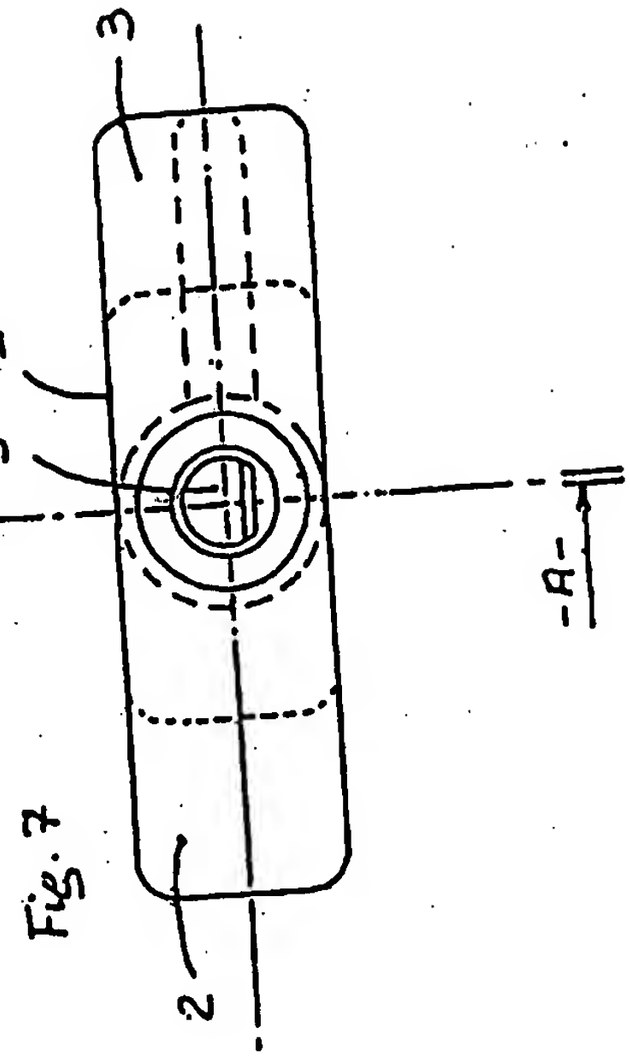

Fig. 7

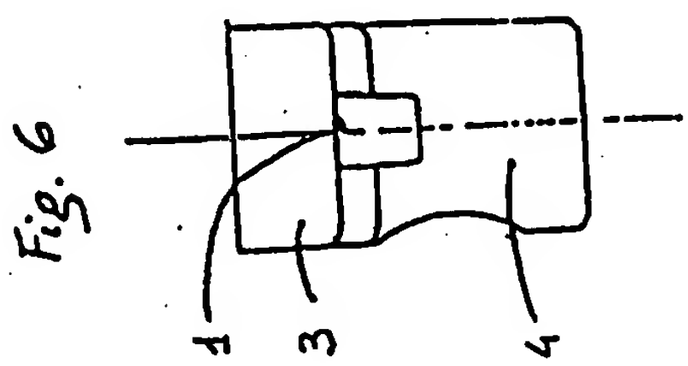

Fig. 6

INTERNATIONAL SEARCH REPORT

Interna al Application No
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A. CLASSIFICATION OF SUBJECT MATTER
IPC 6 A61M15/00

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IPC 6 A61M

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

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C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X Y	EP 0 475 257 A (CHIESI FARMA SPA) 18 March 1992 cited in the application see column 4, line 34 - column 5, line 23; figures	1,5 2,3
Y	GB 1 128 655 A (VANTOREX LTD.) 2 October 1968 see page 2, line 85 - line 99; figure 2	2
Y	US 5 622 162 A (RITSON CARL ET AL) 22 April 1997 see column 14, paragraph 4; figures 3-3B	3
A	US 3 517 667 A (BABBIN SAUL A ET AL) 30 June 1970 see claims 1,2; figures	2

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[X] Further documents are listed in the continuation of box C.

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5 January 1999	14/01/1999

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A	GB 2 276 101 A (CSB MOULDS LTD) 21 September 1994	

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